

#### REMARKS

Claims 1, 3, 5-7, 10, 11, 13-18, 21-23, 25-31, 33, and 34 are pending in this application. Claims 1 and 3 have been amended. Claims 2, 4, 8-9, 12, 19, 20, 24, and 32 have been canceled. New Claim 34 has been added. Support for the amendments and new claim is found in the specification and claims as filed.

#### **Claim Rejections - 35 U.S.C. § 103(a) – Karbachsch in view of Miller**

Claims 1, 3, 5-7, 10, 11, 13-18, 21-23, 25-31, and 33 have been rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 4,983,288 (hereinafter “Karbachs”) in view of U.S. Patent No. 4,906,371 (hereinafter “Miller”).

#### **Pending Claim 1 and its dependent Claims 3, 5-7, 11, 13, 18, 22, 23, 26, and 31**

To establish a *prima facie* case of obviousness, three basic criteria must be met: first, the prior art reference (or references when combined) must teach or suggest all the claim limitations; second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; finally, there must be a reasonable expectation of success. *See* M.P.E.P. § 2143.

Pending independent Claim 1 as amended recites a filter laminate comprising, inter alia, “a first membrane layer comprising a first membrane, wherein said first membrane is a microporous or ultraporous asymmetric membrane, said first membrane having a first surface and a second surface, each of said surfaces comprising pores, and a support region between said first surface and said second surface, said first membrane comprising an asymmetric region comprising flow channels that gradually increase or decrease in diameter from a point in said support region to said second surface, said first membrane further comprising an isotropic region in addition to said asymmetric region, such that said support region comprises a thickness between said first surface and said second surface, wherein said thickness comprises said isotropic region between said first surface and a point within said support region, and an asymmetric region between said point and said second surface, wherein said isotropic region comprises flow channels that are substantially constant in diameter from said first surface to said point between said isotropic region and said asymmetric region, and wherein said asymmetric

region comprises flow channels that gradually increase or decrease in diameter from said point to said second surface.”

Neither Karbachsch nor Miller teaches or suggests a filter laminate incorporating a membrane having the recited pore morphology. As discussed in the attached Declaration of I-fan Wang, a first membrane layer having a combined isotropic and asymmetric structure (“funnel-with-a-neck”) offers advantages over both a pure isotropic structure and a pure asymmetric structure, as disclosed in Karbachsch and Miller. Membranes having a funnel-with-a-neck structure exhibit superior performance in certain aspects when compared to membranes having other pore morphologies. For example, the lateral wicking time is a function of the capillary action that occurs in the horizontal direction of the membrane. Capillary action is greatest in regions where the membrane’s pore sizes are relatively small. In principle, lateral wicking is optimal in a purely isotropic membrane of relatively narrow pore size. Throughout the entire depth of such an isotropic structure, the layers extending in the horizontal direction all contain small pores, which are capable of exerting a relatively strong capillary force. As a result, the lateral wicking rate is rapid at every depth of the membrane, rather than simply at one narrow level, which is the case with the asymmetric structure. A purely isotropic structure, however, suffers from relatively poor filtration capabilities. Large cells are not filtered out prior to contacting the smaller pore openings. Rather, the small pore openings at the surface of an isotropic membrane can cause relatively fragile cells, such as blood cells, to lyse and release their contents. Those contents then mix with and contaminate the plasma. The large blood cells (red blood cells, white blood cells, and platelets) in whole blood will also plug the isotropic structure so as to the blood separation rate is much slower than the asymmetric structure, which, because of its better filtration capabilities, does not have the problem of cells lysing at the layer of small, capillary active pores. Membranes having a funnel-with-a-neck structure exhibit plasma transfer rates superior to those of asymmetric membranes, which is very important in diagnostic testing devices, and filtration capacities superior to those of isotropic membranes. The funnel-with-a-neck structure embodies the advantages of both asymmetric and isotropic structures. Rather than having just a single thin layer of small pores in the middle of the membrane, the funnel-with-a-neck structure has a region of small pores comprising a significant thickness of the membrane’s cross section, comparable to the neck of a funnel. Throughout this region of smaller pores,

lateral wicking occurs in a much shorter time than in regions where the pore sizes are larger. In addition, the tapering region of the funnel-with-a-neck structure serves to filter out the large cells before they can contact the region of small pores, thus eliminating the problem of cells lysing and contaminating plasma prior to lateral wicking – an advantage over isotropic membranes. The funnel-with-a-neck structure exhibits filtration capabilities that are comparable those of classic asymmetric membranes. And because it also demonstrates significantly greater speeds of lateral wicking, the funnel-with-a-neck structure has clear advantages over classic asymmetric membranes in this area.

Because the combination of Karbachsch and Miller fails to disclose all limitations of pending Claim 1, a *prima facie* case of obviousness cannot be established. Even if a *prima facie* case of obviousness were established, the filter laminates incorporating a first membrane as recited in Claim 1 possess superior properties to filter laminates prepared from isotropic membranes and asymmetric membranes such as are disclosed in Karbachsch and Miller. Superiority of a property shared with the prior art is evidence of nonobviousness. See M.P.E.P. § 716.02(a). Accordingly, Applicants respectfully request that the rejection be withdrawn.

**Pending Claim 21 and its dependent Claims 25, 28-30, and 33**

As discussed above, to establish a *prima facie* case of obviousness, the prior art references when combined must teach or suggest all the claim limitations, and there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. See M.P.E.P. § 2143.

Karbachsch and Miller in combination do not teach or suggest all of the limitations of pending Claim 21, which recites a filter laminate comprising, inter alia, “a first membrane layer comprising a first membrane, wherein said first membrane is an asymmetric membrane having a skin surface and an open surface, wherein pores of the open surface are larger than pores of the skin surface; a second membrane layer comprising a second membrane, wherein said second membrane is an asymmetric membrane having a skin surface and an open surface, wherein pores of the open surface are larger than pores of the skin surface; and a bond between each of said adjacent layers, wherein said bond is between the skin surface of the first membrane and the skin surface of the second membrane, wherein the filter laminate has a higher bubble point than either

the first membrane or the second membrane, and wherein the filter laminate has a greater integrity than a combination wherein the skin surface of the first membrane and the skin surface of the second membrane are adjacent to each other but not bonded to each other, wherein the filter laminate has a flow rate therethrough such that the filter laminate is configured for separation by filtration.”

Neither Karbachsch and Miller teaches or suggests a laminate comprising two asymmetric membranes in a skin-to-skin bonded configuration, as recited in Claim 21, much less identify any advantages to such a configuration. As discussed in the application as filed at page 10, ll. 11-21, a skin-to-skin configuration dramatically increases the bubble point of the resulting filter laminate above that of either of the single layers, due to the fact that the probability of lining up two large pores (which are responsible for the bubble point) is significantly reduced because most of the pores are “average” size, and probability greatly favors the situation where a large pore is confronted by numerous smaller pores. This results in greatly improved membrane integrity and, therefore, improved bacterial and particle retention. Simply placing two asymmetric membranes together, skin-to-skin, without bonding them, will not necessarily reduce the bubble point because the test air that flows through the top layer can travel laterally until it finds a larger pore in the bottom layer.

Because the combination of Karbachsch and Miller fails to disclose all limitations of pending Claim 21, a *prima facie* case of obviousness cannot be established. Even if a *prima facie* case of obviousness were established, the filter laminates having a skin-to-skin bonding configuration between two asymmetric membranes recited in Claim 21 possess superior properties to filter laminates such as are disclosed in Karbachsch and Miller. Greater than expected results are evidence of nonobviousness. See M.P.E.P. § 716.02(a). Accordingly, Applicants respectfully request that the rejection be withdrawn.

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**Conclusion**

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: \_\_\_\_\_

11/14/07

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